

REMARKS

Claims 1-4, 6-14, and 16-21 are currently pending in the application.

The amendment to claim 4 is supported by the specification and does not add new matter.<sup>1</sup>

In view of the above, accordingly, claim 4 has been amended solely for the purpose of prosecuting the amended claim in this application. This amendment better encompasses the full breadth of certain aspects of the present invention, notwithstanding Applicants' belief that the original claim would have been allowable.

I. 35 U.S.C. 112, First Paragraph Rejection

Reconsideration is requested of the rejection of claims 4, 12-14, and 21 under 35 U.S.C. 112, first paragraph. In support of this rejection, the Office has asserted that these claims are not enabled because they are directed toward novel viral strains that are not obtainable by a repeatable method. The Office also notes that the enablement requirement may be satisfied by a deposit of the claimed viral strains.

Claim 4, as amended, is now directed toward only viral strains that have been deposited with the ATCC as indicated in the specification.<sup>2</sup> Claims 12-14, and 21, which are directed toward vaccines and methods employing the viral strain of claim 4, are also now only directed toward the use of viral strains that have been deposited. Accordingly, it is hereby certified that viral strains C3464 (ATCC Accession No. PTA-1471), C3490 (ATCC Accession No. PTA-1473), and C3605 (ATCC Accession No. PTA-1472), as set forth in claim 4, have been deposited under the Budapest Treaty and these strains will be irrevocably and without condition or restriction be released to the public upon the issuance of a patent.

<sup>1</sup>See page 7, lines 1-5 of the Specification.

<sup>2</sup>Enclosed is a copy of the ATCC deposit certificate evidencing the deposit of the claimed viral strains.

In view of the claim amendments and the deposit of all viral strains claimed, the basis for this rejection has been removed.

## II. 35 U.S.C. 102(e) Rejection

Reconsideration is requested of the rejection of claims 1 and 18 under 35 U.S.C. 102(e) in view of Cates.<sup>3</sup>

Claim 1 is directed toward an isolated, **attenuated** viral strain of human parainfluenza virus 2 and claim 18 is directed toward a method of inducing an immune response employing the isolated, **attenuated** viral strain of claim 1.

Cates, on the other hand, generally discloses hemagglutinin-neuraminidase (HN) and fusion (F) **glycoproteins** isolated and purified from **non-attenuated** parainfluenza viruses types 1, 2, and 3. Additionally, Cates discloses methods and vaccines employing these glycoproteins.

Claims 1 and 18, accordingly, are not anticipated by the Cates disclosure. The Office, however, in support of its rejection asserts that "Cates et al. teach a HPIV-2 attenuated strain (isolated HN and F glycoproteins)."<sup>4</sup> This assertion is not correct. Nowhere does Cates disclose attenuated HPIV-2 strains. Cates merely discloses, as stated above, the isolation of two **glycoproteins** from **dead, non-attenuated** viral strains. Claims 1 and 18, on the other hand, are directed toward **attenuated** viral strains. "Attenuated" as generally known in the art and as defined in the specification, is a mutant viral strain that has been selected phenotypically for cold adaptation and temperature sensitivity relative to wild type strains.<sup>5</sup> Importantly, the viral strains claimed in the present invention are **alive** and are not isolated proteins from non-attenuated viral strains, as disclosed in Cates.

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<sup>3</sup>Cates et al., U.S. Patent No. 6,165,774.

<sup>4</sup>See Paper 5, at page 3.

<sup>5</sup>See page 4, lines 1-10 of the Specification.

Because the cited art does not disclose each and every element of the invention defined by claims 1 and 18, the rejection of these claims on the basis of anticipation is not proper. Accordingly, Applicants respectfully traverse this basis of rejection and request its reconsideration and withdrawal.

II. Conclusion

In light of the foregoing, Applicants request entry of claim amendments, withdrawal of claim rejections, and solicit an allowance of the claims. The Examiner is invited to contact the undersigned attorney should any issue remain unsolved.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

**Claim 4:**

4. (once amended) The isolated, attenuated viral strain of claim 1 which is selected from the group of viral strains consisting of those designated [C3396,] C3464, C3490, [C3457,] [C3440,] C3605 -[C3444], and subclones or progeny of any of the aforementioned strains.

**Claim 5:**

Canceled.

**Claim 15:**

Canceled.

**Claim 22:**

Canceled.

~~It is believed that no fee is required. If, however, there~~  
are any fees associated with this Amendment A and Response, the  
Commissioner is hereby authorized to charge Deposit Account No.  
19-1345.

Respectfully submitted,



Kathryn J. Doty, Reg. No. 40,593  
SENNIGER, POWERS, LEAVITT & ROEDEL  
One Metropolitan Square, 16th Floor  
St. Louis, Missouri 63102  
(314) 231-5400

KJD/rle

Express Mail No.: EL910280724US

**ATCC**

'00 JUN 26 AM 9 31

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

#C  
Micro Rep. Station  
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TECH CENTER 1600/2900

To: (Name and Address of Depositor or Attorney)

St. Louis University  
Attn: Robert O. Webster, Ph.D.  
3556 Caroline, Room 110  
St. Louis, MO 63104

Deposited on Behalf of:

St. Louis University, Technology Transfer Office, St. Louis  
University School of Medicine

## Identification Reference by Depositor:

Human Parainfluenza virus type 2, Clone 3464, Pool 619, PIV2,  
C3464, CP50, EPP2, SLU 7255

Human Parainfluenza virus type 2 Clone 3605 Pool 620, PIV2,  
C3605, CP47, SLU 7255

Human Parainfluenza virus type 2 Clone 3490 Pool 621, PIV2,  
C3490, cp63, SLU 7255

Human Parainfluenza virus type 2 WILD TYPE, Pool 622, PIV2,  
wild type, SLU 7255

## Patent Deposit Designation

PTA-1471

PTA-1472

PTA-1473

PTA-1474

The deposits were accompanied by: \_\_\_ a scientific description, a proposed taxonomic description indicated above.  
The deposits were received March 9, 2000 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 21, 2000. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara E. Coupé, Administrator, Patent Depository

Date: June 22, 2000

cc: Senninger, Powers, Leavitt & Roedel (Ref. Docket SLU 4505)